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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|------------------------|---------------------|------------------|
| 09/821,831      | 03/30/2001  | Perry Francis Bartlett | 3206.1001-000       | 6242             |

21005 7590 07/09/2003

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.  
530 VIRGINIA ROAD  
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CONCORD, MA 01742-9133

EXAMINER

HAYES, ROBERT CLINTON

ART UNIT PAPER NUMBER

1647

DATE MAILED: 07/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.



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**Office Action Summary**

Application No.

09/821,831

Applicant(s)

BARTLETT ET AL.

Examiner

Robert Hayes

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1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period of Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-17 (each in part), drawn to an isolated nucleic acid molecule comprising SEQ ID NO: 3 and genetic constructs comprising same, classified in class 514, subclass 44, for example.
  - II. Claims 1-17 (each in part), drawn to an isolated nucleic acid molecule comprising SEQ ID NO: 5 and genetic constructs comprising same, classified in class 514, subclass 44, for example.
  - III. Claims 1-17 (each in part), drawn to an isolated nucleic acid molecule comprising SEQ ID NO: 7 and genetic constructs comprising same, classified in class 514, subclass 44, for example.
  - IV. Claims 1-17 (each in part), drawn to an isolated nucleic acid molecule comprising a nucleotide sequence encoding the amino acid sequence of SEQ ID NO: 8 and genetic constructs comprising same, classified in class 514, subclass 44, for example.
  - V. Claims 18, 24-26, and 28-30 (each in part), drawn to a method of inhibiting, reducing, or otherwise antagonizing p75NTR-mediated death signal in a cell, said method comprising administering a peptide, classified in class 514, subclass 2, for example.
  - VI. Claims 19 and 22 drawn to a peptide comprising the amino acid sequence of SEQ ID NO: 8, classified in class 514, subclass 2, for example.

- VII. Claims 20 and 21 (each in part), drawn to a recombinant peptide comprising the amino acid sequence encoded for in SEQ ID NO: 3, classified in class 514, subclass 2, for example.
- VIII. Claims 20 and 21 (each in part), drawn to a recombinant peptide comprising the amino acid sequence encoded for in SEQ ID NO: 5, classified in class 514, subclass 2, for example.
- IX. Claims 20 and 21 (each in part), drawn to a recombinant peptide comprising the amino acid sequence encoded for in SEQ ID NO: 7, classified in class 514, subclass 2, for example.
- X. Claims 23-30 (each in part), drawn to a method of inhibiting, reducing, or otherwise antagonizing p75NTR-mediated death signal in a cell, said method comprising introducing a nucleic acid molecule, classified in class 514, subclass 44, for example.

2. The inventions are distinct, each from the other because of the following reasons:

3. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions V and X are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention V requires search and consideration of administering a peptide, which is not required by Invention X. Invention X

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requires search and consideration of introducing a nucleic acid molecule, which is not required by Invention V.

4. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Inventions I, II, III, IV, VI, VII, VIII, and IX are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. The isolated nucleic acid molecule of Invention I is independent and distinct from the products of Inventions II, III, IV, VI, VIII, and IX because it is not required to make the isolated nucleic acid molecule of Invention I. Although the nucleic acid molecule of Invention I can be used to obtain the peptide of Invention VII it can also be used in materially different methods, such as a probe in nucleic acid hybridization assays or therapeutic methods (e.g. gene therapy). The isolated nucleic acid molecule of Invention II is independent and distinct from the products of Inventions I, III, IV, VI, VII, and IX because it is not required to make the isolated nucleic acid molecule of Invention II. Although the nucleic acid molecule of Invention II can be used to obtain the peptide of Invention VIII it can also be used in materially different methods, such as a probe in nucleic acid hybridization assays or therapeutic methods (e.g. gene therapy). The isolated nucleic acid molecule of Invention III is independent and distinct from the products of Inventions I, II, IV, VI, VII, and VIII because it is not required to make the isolated nucleic acid molecule of Invention III. Although the nucleic acid molecule of Invention III can be used to obtain the peptide of Invention IX it can also be used in materially different methods, such as a probe in nucleic acid hybridization assays or therapeutic methods (e.g. gene therapy). The

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isolated nucleic acid molecule of Invention IV is independent and distinct from the products of Inventions I, II, III, VII, VIII, and IX because it is not required to make the isolated nucleic acid molecule of Invention IV. Although the nucleic acid molecule of Invention IV can be used to obtain the peptide of Invention VI it can also be used in materially different methods, such as a probe in nucleic acid hybridization assays or therapeutic methods (e.g. gene therapy). The peptide of Invention VI is independent and distinct from the products of Inventions I, II, III, VII, VIII, and IX because it is not required to make the peptide of Invention VI. The peptide of Invention VII is independent and distinct from the products of Inventions II, III, IV, VI, VIII, and IX because it is not required to make the peptide of Invention VII. The peptide of Invention VIII is independent and distinct from the products of Inventions I, III, IV, VI, VII, and IX because it is not required to make the peptide of Invention VIII. The peptide of Invention IX is independent and distinct from the products of Inventions I, II, IV, VI, VII, and VIII because it is not required to make the peptide of Invention IX.

5. Inventions I and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product. The nucleic acid molecules of Invention I can be used as a probe in nucleic acid hybridization assays.

6. Inventions II and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

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product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product. The nucleic acid molecules of Invention II can be used as a probe in nucleic acid hybridization assays.

7. Inventions III and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product. The nucleic acid molecules of Invention III can be used as a probe in nucleic acid hybridization assays.

8. Inventions IV and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product. The nucleic acid molecules of Invention IV can be used as a probe in nucleic acid hybridization assays.

9. Inventions VI and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product



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as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product. The polypeptide of Invention VI can be used to isolate receptors.

10. Inventions VII and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product. The polypeptide of Invention VII can be used to isolate receptors.

11. Inventions VIII and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product. The polypeptide of Invention VIII can be used to isolate receptors.

12. Inventions IX and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product. The polypeptide of Invention IX can be used to isolate receptors.

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13. Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions I and V are unrelated product and method, wherein each is not required, one for another. For example, the claimed method of Inventions V does not recite the use or production of the nucleic acids of Invention I.

14. Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions II and V are unrelated product and method, wherein each is not required, one for another. For example, the claimed method of Inventions V does not recite the use or production of the nucleic acids of Invention II.

15. Inventions III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions III and V are unrelated product and method, wherein each is not required, one for another. For example, the claimed method of Inventions V does not recite the use or production of the nucleic acids of Invention III.

16. Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions IV and V are unrelated product and method, wherein each is not

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required, one for another. For example, the claimed method of Inventions V does not recite the use or production of the nucleic acids of Invention IV.

17. Inventions VI and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions VI and X are unrelated product and method, wherein each is not required, one for another. For example, the claimed method of Inventions X does not recite the use or production of the peptide of Invention VI.

18. Inventions VII and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions VII and X are unrelated product and method, wherein each is not required, one for another. For example, the claimed method of Inventions X does not recite the use or production of the peptide of Invention VII.

19. Inventions VIII and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions VIII and X are unrelated product and method, wherein each is not required, one for another. For example, the claimed method of Inventions X does not recite the use or production of the peptide of Invention VIII.

20. Inventions IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different

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functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions IX and X are unrelated product and method, wherein each is not required, one for another. For example, the claimed method of Inventions X does not recite the use or production of the peptide of Invention IX.

21. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

22. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Hayes whose telephone number is 703-305-3132. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D. can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN  
September 25, 2002

*Gary A. Kunz*  
**GARY KUNZ**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**